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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/16/2005

Hamid Sharim

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THE NATH LAW GROUP

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EXAMINER

COMSTOCK, DAVID C

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,901	Applicant(s) SHARIM, HAMID	
	Examiner DAVID COMSTOCK	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brace et al (US Pat 6235033).

Regarding Claim 1: Brace et al. teach a saddle clamp/bone fixation assembly having a rigid body having a contact surface (Figure 1 Element 10) with at least two holes (Figure 3 Element 24, shown as at least two holes in Figure 2), at least one assembly element (Figure 12 Element 34) with at least two of said holes passing through said contact surface (Figure 1).

Regarding Claim 2: Brace et al. teach a device where the axes of two of said holes converge towards said bone (Figure 2).

Regarding Claim 3: Brace et al. teach an assembly element that is a threaded pin protruding from said rigid body (Figure 6 Element 34).

Regarding Claims 5 and 7: Brace et al. teach a device having a saddle shaped surface and a second surface (Figure 2) with first and second passing holes.

Regarding Claims 6 and 8: Brace et al. teach a contact surface and a second surface being an arcuate surface (Figure 2) and at least two holes are directed perpendicular to the bone's axes (Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al (US Pat 6235033) as set forth regarding claims 1-3 and 5-8 and further in view of Dixon et al (US PGPub 2003/0135210).

Regarding Claim 4: Brace et al. teaches the basic claimed device as set forth in the rejections above. Brace et al. does not teach an assembly element that is a threaded nut. Dixon et al. teach an assembly element that is a threaded nut built into said rigid body (Paragraph 42). Brace et al. and Dixon et al. are analogous art because they are from the same field of endeavor of spinal stabilization devices. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Dixon et al.'s nut in Brace et al.'s device. The motivation would have been to offer an equivalent and alternative means of securing the device to the bone.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al (UP Pat 6235033).

Brace et al. teach the basic claimed device as set forth above regarding claim 1 and claim 8.

Brace et al. teach a device where holes would be drilled into the bone (at a surgeon-selected orientation Column 2 Lines 40 through 60) in order to secure the

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fixation device to said bone, indicating that there could be an intersection of the axes. Brace et al. does not teach an intersection of the axes occurring at an angle between 45 and 60 degrees. See MPEP 2144.05 Section II B. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use this range in angular degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claims 10 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al (US Pat 6235033) as set forth above regarding claims 1-3 and 5-8 and further in view of Dixon et al (US PGPub 2003/0135210) as applied to Claim 1 above.

Regarding Claims 10 and 11: Brace et al. does not teach a method for mounting the saddle clamp to the bone. Dixon et al. discloses a method providing a saddle clamp/stabilizer having a contact surface and holes for said bone (Figure 1), fixing elements (Figure 1 Elements 40 and 47), exposing a suitable area of said bone (which is well known in the art if a surgeon is to perform an invasive surgery like this), drilling holes in said bone (Paragraph 75), and mounting said device on said bone (Paragraph 75). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Dixon et al.'s method with Brace et al.'s device. The motivation would have been to offer an equivalent and alternative means of securing the device to the bone.

Regarding Claim 12: Brace et al. teach the basic claimed device as set forth in the rejections above. Brace et al. teach vertebrae, which are substantially tubular bones, since the spinal cord runs through them, and a device that can be attached to

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the vertebrae (Figure 12). Anything being fixated to the vertebral body will essentially be perpendicular to the axis, which runs parallel to the spinal cord.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al (US Pat 6235033) in view of Dixon et al. (US PGPub 2003/0135210) as set forth above regarding claims 10 and 11 and further in view of Itoman et al (US Pat 5665086) as applied to claim 10 above.

Regarding Claim 13: Brace et al. does not teach an intersection of the axes of the holes in the tubular bone occurring at an angle between 45 and 60 degrees. See MPEP 2144.05 Section II B. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use this range in angular degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brace et al. (US Pat 6235033) in view of Dixon et al. (US PGPub 2003/0135210) as applied to Claim 10 above, further in view of Bryan (US Pat 5306275).

Regarding Claims 14, 17, and 18: Brace et al. teach a similar device as explained in the rejections above. Brace et al. does not teach a method including a saddle clamp with a saddle surface, a second surface, a first and second passing holes, and fixing elements that are screws. Bryan teaches a method including a saddle clamp/hook (Figure 1 Element 14), a second surface (Figure 1 Element 12), first and second passing holes (Elements 80a and 80b), fixing elements (Figure 1 Element 20) that are screws, drilling pilot holes in the vertebrae corresponding to said passing holes

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(Column 14 Lines 45 through 55) and mounting the clamp on the vertebrae (Column 15 Lines 25 through 40). Brace et al. and Bryan are analogous art because they are from the same field of endeavor of spinal stabilization devices. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Bryan's method for Brace et al.'s device. The motivation would have been to offer an alternative and equivalent means of securing the device to the bone.

Regarding Claim 15: Brace et al. does not teach a method where the second surface of the clamp is an arcuate surface. Bryan teaches a method where the second surface of the clamp is an arcuate surface (Figure 1). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Bryan's surface shape in Brace et al.'s device. The motivation would have been to offer an equivalent and alternative means of securing the device to the bone.

Regarding Claim 16: Brace et al. does not teach a method of adjusting the surface of the vertebrae. Bryan teaches a method of cutting away bone (Column 14 Lines 40 through 50). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Bryan's method with Brace et al.'s device. The motivation would have been to offer an equivalent and alternative means of securing the device to the bone.

Response to Arguments

Applicant's arguments filed 15 February 2009 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a shape comprising a "hyperbolic paraboloid", see page 4, line 1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, regarding the intended definition of "saddle clamp," it is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01. Since a "saddle" can be nothing more than a generally arcuate surface, additional limitations directed to another arc or to hyperbolic paraboloids should not be read into the claims in the interpretation thereof. As such, there is no reason why the device of Brace et al. cannot be seen as satisfying the broad limitation "saddle clamp." Moreover, the locking screw 34 is integral with the bone fixation device at least as by assembly therewith via the fastening screw 32. In addition, the device of Brace et al. is at least capable of being used in the claimed intended manner. For example, depending on the frame of reference, the position on a

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patient, and the orientation of the device, Brace et al. can comprise at least three spaced apart non-collinear areas of contact that can be engaged by tightening two fixing elements (e.g., the central region of the base of the plate, the region of a screw on one side, and the region of a screw on an opposite side via the two corresponding screws). It is also noted that the screw would protrude at least during assembly and disassembly. Regarding the intended use of the device, there is nothing to preclude the device of Brace et al. from being clamped in any desired location (e.g., so as to straddle the top of the pedicle between a transverse process and a superior facet). What is meant by "built into" has not been clearly defined by Applicant. It appears that threading the nuts onto the device can be considered "built into," since threading is one process by which mechanical assemblies are built. Regarding the rejection over Brace et al. in view of Dixon, Applicant has not articulated why the device of Dixon is allegedly not suited for any deformation. It is noted that all materials are subject to at least some degree of deformation under loading. Therefore, Applicant's unsupported conclusion that the combined references "do not work" is not accepted. Moreover, Examiner agrees that spinal cords are not a bone. However, that is not the argument made in the rejection. The rejection simply advances that the bones of the vertebral column constitute a tubular structure owing to the space for the spinal cord (the vertebral foramen).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733